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EXAMINER	
ABRAHAM, SALIEU M	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,540	XUE ET AL.	
	Examiner	Art Unit	
	SALIEU M. ABRAHAM	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-10,12,13,15-17 and 19-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-10,12-13, 15-17 and 19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks/Arguments

1. Examiner acknowledges Applicant's cancellation of claims 6-7, 11, 14,18 and 27 and amended claims 1, 3, 8, 10, 12, 13, 15, 16, 20 and 23. Further, examiner withdraws prior claim objections in light of applicant amendments. Therefore claims 1- 5, 8 -10, 12-13, 15-17 and 19 - 26 are currently pending.

2. Upon further review of the art of record and in light of the cancelled and amended claims, the prior indication of allowable subject matter for claim 12 is hereby withdrawn and new grounds of rejection have been made as articulated in the detailed action below.

3. Applicant's arguments with regard to claims 1- 5, 8 -17, 19 - 26 filed September 13, 2008 have been fully considered, but they are not persuasive in light of the new grounds of rejection. The new grounds of rejection were met by art of record and as such did not require an updated or new search.

4. The instant Office Action is made **non-final** in light of the withdrawal of allowable subject matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1- 5, 8 -10, 12-13, 15-17 and 19 - 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pub. No. US 2003/0093067 A1 to Panescu (Panescu) in view of US Pat. No. 6,301,496 B1 to Reisfield (Reisfield).

In Reference to Claim 1

Panescu teaches a method comprising "acquiring an image pertaining to a heart (**see abstract, figure 7A, and sections 0004 and 0007**). Panescu further teaches the step of "registering a representation of a probe which is in or adjacent to the heart with the image (**sections 0007 and 0009**). However Panescu fails to disclose the step of "wherein the heart vector represents a summation of electrical currents at a particular time, the summation having a direction and amplitude and generated from data acquired by a lead system at a surface of an imaged subject with the heart."

Reisfeld, in the same field of endeavor, teaches the utilization of heart vectors in order to aid in diagnosing cardiac arrhythmias (**see abstract and figures 5, 10-14**) and improve heart/cardiac mapping in order to better tag and locate areas with "aberrant

electrical pathways and currents within the heart (**see column1, lines 14-18, and column 2, lines 7-36**). He further discloses for acquisition of the electrical activity data "wherein the heart vector represents a summation of electrical currents at a particular time, the summation having a direction and amplitude and generated from data acquired by a lead system at a surface of an imaged subject with the heart." (**see abstract and figures 5, 10-14 and columns 2, lines 1-67, 14, lines 1 - 39 and 19, lines 56 - 67**)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the step of " "registering a representation of a probe which is in or adjacent to the heart with the image using a heart vector of the heart" of Reisfeld in the image acquisition/probe registration method according to Panescu in order to improve methods for cardiac mapping in order to better locate deficient functional areas of the heart for probe placement in electrophysiological studies (see column 1, lines 14-18, and column 2, lines 7-36,) as explicitly taught by Reisfeld.

In Reference to Claim 2

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim1. Panescu further teaches the step of "further comprising simultaneously displaying the registered image, the registered representation of the probe, and a map of the electrical properties of the heart" **(see sections 0050 for function of mapping device < device**

shown by reference mark 142 in figure 1> and 0007 and 0008 for limitation).

Because the three-dimensional map described in various sections (**see for example 0007 ,0008**) of Panescu, present a 3D mapping of locations of irregular electrical heart activity (**see section 0050**), it follows that these locational mappings constitute mappings of "electrical properties of the heart."

Therefore, Panescu in view of Reisfeld teaches all claim 2 limitations as well.

In Reference to Claims 3 and 4

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 2. Panescu further teaches the step "wherein the image is acquired using computed tomography, magnetic resonance, or ultrasound." (**see sections 0008 and at bottom of page1**).

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim1. Additionally, Panescu in view of Reisfeld has been also been shown to teach the step "wherein the registering step comprises registering data pertaining to one or more locations of the heart vector which is correlated with the image with data pertaining to one or more locations of the heart vector which is correlated with the representation of the probe." (**see Panescu section 0007 and Reisfeld column 3, lines 45-57**).

In Reference to Claim 5

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim1. Panescu further teaches the step "wherein the probe is configured to sense electrical

information pertaining to the heart." (**see section 0050**).

In Reference to Claim 12

Panescu in view of Reisfeld teaches:

a) acquiring an image of or pertaining to a heart; and

b) registering a representation of a probe which is in or adjacent to the heart with the image using a heart vector of the heart. (**see claim rejections supra**)

Panescu further teaches the acquisition of multiple data sets from the heart to include location specific data (**see sections 0007-0010 and 0059-0061**), in order to register a representation of a probe along with an image of the heart (**see sections 0006 and 0007**). Panescu further teaches that two data sets can be acquired: 3D image data and 3D (deficient electrical areas) mapping of the heart or other internal body organ of study (**see section 0007**). Also, two respective location data sets can be acquired with/in addition to the image and mapping data in order to correlate overall heart and heart defective area locations(**see fourth embodiment in section 0010**). However, Panescu fails to teach the probe and heart image *registration and mapping* (e.g. the 3D heart image and map location data) being accomplished through the use of heart vectors according to claim 12.

As described before, Reisfeld teaches 3D vector mapping of internal body organs such as the heart in order to better locate deficient functional areas of the heart for probe placement in electrophysiological studies (**see column 1, lines 14-18, and column 2, lines 7-36**). He further discloses "wherein the location of the heart vector from the second data set can be determined relative to the lead, and wherein the location of the probe can also be determined relative to the lead." (**see abstract, figures 1 and 2 and column 17, lines 1- 5**)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have substituted the step of 3D vector mapping of the heart of Reisfeld in the method of mapping the (dual) heart and heart map location data sets of Panescu in order to improve the locating of "aberrant electrical pathways" in the heart by medical personnel as explicitly taught by Reisfeld.

In Reference to Claim 8

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim12. Reisfeld further teaches the step wherein "the registering includes
registering the location of a first heart vector from the first data set relative to the lead system, registering a second heart vector from the second data set relative to the lead system, and registering the first heart vector from the data set relative to the second heart vector from the data set" (**see column 17, lines 37- 47**).
Therefore, Panescu in view of Reisfeld further teaches all claim 8 limitations.

In Reference to Claim 9

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 8. Reisfeld further teaches that a plurality of locations related to vector mapping of the heart "are determined at a common point in the cardiac cycle, preferably at end diastole." Because end-diastole includes a portion of the QRS complex, Reisfeld therefore also teaches the step "wherein the portion of the cardiac cycle comprises at least a portion of the QRS portion (**see column 17, lines 28-37**).

Therefore Panescu in view of Reisfeld further teaches all claim 9 limitations as well.

In Reference to Claim 10

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 12. Panescu further teaches the step "wherein the probe is configured to sense the electrical properties of the heart" (**see section 0050**).

Therefore Panescu in view of Willis further satisfies all claim 10 limitations as well.

In Reference to Claim 13

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 12. Furthermore, Panescu also teaches the step "wherein the image comprises one or more images obtained using computed tomography, magnetic resonance, or ultrasound" (**see section 0008**).

Therefore Panescu in view of Reisfeld further teaches all claim 13 limitations as well.

In Reference to Claims 15

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 12. Furthermore, Reisfeld also teaches the step "wherein the acquiring the second data step and the registering step are performed on a repeating basis". (**see figures 1 and 2, reference marks 20, 24, 26 and 28 and column 16, lines 1 - 42**).

Therefore Panescu in view of Reisfeld further teaches all claim 15 limitations as well.

In Reference to Claim 16

The combination of Panescu and Reisfeld disclose all claim 16 limitations (**see claim 1 and 12 rejections supra**) except "adjusting the size or position of the image dependent on a change in the location of the first and second heart vector generated from the first and second data sets, respectively." (**see Reisfeld columns 24, lines 60 - 67, and 25, lines 1- 26**).

In Reference to Claim 17

See rejections in claims 16 and 1.

In Reference to Claim 19

See Reisfeld columns 24, lines 60 - 67, and 25, lines 1- 26.

In Reference to Claim 20

Panescu teaches a system comprising:

- a processor configured to be communicatively coupled to a probe, the probe being configured to be located in or adjacent to a heart; (see figure 1, reference marks 124 and 126 and sections 0039-0042).

- "memory configured to store: an image of at least a portion of the heart; a first data set pertaining to one or more locations of a heart vector of the heart, the first data set being spatially correlated with the image;

  a second data set pertaining to one or more locations of the heart vector of the heart;

  a display configured to display the image and a representation of the probe, the image being registered with the representation of the probe by registering the heart vector from the first data set with the heart vector from the second data set. (see figure 1, reference marks 104, 166, 102 and 126 and sections 0039-0042).

- a display configured to display the image and a representation of the probe, the image being registered with the representation of the probe by registering the heart vector from the first data set with the heart vector from the second data set. (see figure 1, reference marks 106 and 146 and sections 0012-0013).

Note: The memory (structure) depicted in figure 1 of Panescu is configured to store data from a plurality of sources and there is no reason to preclude data sets related to heart vectors. The heart vector data set storage is not limiting on the Panescu structure of the Panescu memory. Furthermore, the display of Panescu has been shown to be capable of displaying a registered probe with image. How this

capability is achieved, is also not limiting on the display's capability to display the data once acquired.

Reisfeld teaches a lead system located at a surface of an imaged subject and operable to acquire multiple data sets from multiple locations dependent upon corresponding heart vector locations. (**see figures 1 and 10 -14**)

Resifeld further teaches "wherein the location of the heart vector from the second data set can be determined relative to the lead, and wherein the location of the probe can also be determined relative to the lead." (**see column2, lines 1- 30, lines 59 - 63**).

Therefore, Panescu in view of Reisfeld further teaches all claim 20 limitations

In Reference to Claim 21

Panescu in view of Reisfeld has been shown to teach all limitations of 20. Panescu further teaches:

- the system of claim 20, wherein the display is configured to display a map of electrical properties of the heart in conjunction with the image and representation of the probe (**see sections 0050 for function of mapping device < device shown by reference mark 142 in figure 1> and 0007 and 0008 for limitation).; also see discussion at end of claim 2 rejection**).

Therefore, Panescu in view of Reisfeld further teaches all claim 21 limitations

In Reference to Claim 22

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 20. Reisfeld further teaches of 3D heart vector mapping employing a plurality of electrocardiogram leads (**see column 17, lines 1-5**) in order to further analysis of the "functioning heart" and allow a physician to "decide on a required treatment accordingly" (**see column 18, lines 45-52**).

Therefore, Panescu in view of Reisfeld further teaches all claim 22 limitations.

In Reference to Claim 23

Panescu in view of Reisfeld has been shown to teach all of the limitations of claim 20 (e.g. a system capable of acquiring heart images and registering a probe representation with it based on using heart vectors). Furthermore, Panescu in view of Reisfeld has been shown to teach the method "wherein the representation of the probe is registered with the image by registering the first heart vector from the first data set with the second heart vector from the **second data set for at least a portion of the cardiac cycle" (see column 17, lines 37-47**).

Therefore, Panescu in view of Reisfeld further teaches all claim 23 limitations.

In Reference to Claim 24

Panescu has been shown to teach all of the limitations of claim 20 (**e.g. a system capable of acquiring heart images and registering a probe representation with it based on using heart vectors per claim rejections supra**). Furthermore, Panescu in view of Reisfeld has been shown to teach the method "wherein the portion of the cardiac cycle comprises at least a portion of the QRS segment" (**see earlier claim 9 rejection**).

Therefore, since Panescu in view of Reisfeld teaches both the apparatus and method for the step "wherein the portion of the cardiac cycle comprises at least a portion of the QRS segment" (see earlier claim 9 rejection), it further teaches all claim 24 limitations.

Therefore, Panescu in view of Reisfeld further teaches all claim 24 limitations.

In Reference to Claim 25

Panescu in view of Reisfeld has been shown to teach all limitations of 20. Panescu further teaches the system of claim 20 "wherein the system is an electrophysiology monitoring system (**see abstract, figures 1, 7-9, and sections 0007-0011, 0034, and 0050**).

Therefore, Panescu in view of Reisfeld further teaches all claim 25 limitations.

In Reference to Claim 26

Panescu in view of Reisfeld has been shown to teach all limitations of 20. Panescu further teaches that heart mapping data can be spatially correlated with a probe used for electrophysiological study of the heart (**see sections 0007 and 0010**). Panescu

also teaches an embodiment (**fourth; see section 0010**) whereby two sets of location data can be acquired for guiding probes such as catheters using registered images. Therefore, Panescu in view of Reisfeld further teaches all claim 25 limitations.

7. Claims 1- 5, 8 -10, 12-13, 15-17 and 19 - 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,896,657 to Willis (Willis) in view of US Pat. No. 6,301,496 B1 to Reisfield (Reisfield).

In Reference to Claims 1- 5, 8 -10, 12-13, 15-17 and 19 - 26

Willis teaches substantially all claim limitations (**see abstract, figures 1, 30 - 35 and column 2, lines 1 - 47**) with the exception of explicitly disclosing heart vector usage for facilitating registration and mapping.

Reisfeld teaches 3D vector mapping of internal body organs such as the heart in order to better locate deficient functional areas of the heart for probe placement in electrophysiological studies (**see column 1, lines 14-18, and column 2, lines 7-36**). He further discloses "wherein the location of the heart vector from the second data set can be determined relative to the lead, and wherein the location of the probe can also be determined relative to the lead" (**see abstract, figures 1 and 2 and column 17, lines 1- 5**) in addition to registering a static or dynamic image representation of the heart (**see columns 5, lines 58- 67 and 6, lines 1-35**).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have substituted the step of 3D vector mapping of the heart of Reisfeld

in the method of mapping and registering heart images of Willis in order to better locate deficient functional areas of the heart for probe placement in electrophysiological studies by medical personnel as explicitly taught by Reisfeld.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Xue et al., Chenal et. al., Willis et. al., Osadchy et al., Panescu et al. and Nolte et al. have been included because they all encompass MR, CT or ultrasound imaging systems and methods that are strongly related to electrophysiology studies and applications as described by the applicant. Additionally, Pearlman has been included because his invention involves imaging methodology and apparatus that reconstructs a single composite image or image set from two images or image sets at different time points. This is done in order to enhance or more accurately display any event(s) that transpired between the image acquisition time points.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 8:30 am - 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SA 8/18/08

/Brian L Casler/
Supervisory Patent Examiner, Art Unit 3737